UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,882	03/08/2004	David Radunsky	067062.0127	2882

31625 7590 06/10/2005

BAKER BOTTS L.L.P.
PATENT DEPARTMENT
98 SAN JACINTO BLVD., SUITE 1500
AUSTIN, TX 78701-4039

EXAMINER	
DRODGE, JOSEPH W	

ART UNIT	PAPER NUMBER
1723	

DATE MAILED: 06/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/796,882	RADUNSKY ET AL.	
	Examiner	Art Unit	
	Joseph W. Drodge	1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-17 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-17 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 0404,0505.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The disclosure is objected to because of the following informalities: Page 1 lacks the necessary reference to the parent application having matured into patent 6,787,040.

Appropriate correction is required.

The abstract of the disclosure is objected to because it is not directed to all of the instantly claimed inventions including the replacement fluid composition. Correction is required. See MPEP § 608.01(b).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1,2,5,6,7,10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Bene et al patent 5,578,223.

Bene et al disclose a replacement blood fluid that is "sterile", hence inherently of pharmaceutical grade or clean and contains target receptor molecules, such as antibodies or other substances (column 1, lines 20-26 and column 7, lines 29-37).

For claims 2 and 7, presence of a particular hemofilter for treating fluid other than the replacement fluid claimed is not a limitation for the claimed fluid.

For claims 5 and 10, see Bene at column 1, line 20 for plural antibiotics.

For claim 11, hemofiltration is mentioned at least at column 1, line 50 and column 6, line 26, while figures 1 and 2 show couplings.

Claims 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al patent 5,571,418.

Lee et al disclose a blood membrane filter or hemofilter operable to remove relatively large molecular weight complex molecules from blood with a molecular weight cutoff of 100 to kiloDaltons (column 2, lines 1-26 and 50-61 and column 4, lines 25-32 and 49-54 are especially pertinent).

If necessary, the MW cutoff of Lee et al touches the MW cutoff range described in the instant Specification at page 22, lines 6-30 (MW cutoff of 150-500 kilodalton). Since the respective ranges are touching, Lee et al is considered to anticipate the claimed range as Lee et al also teaches with specificity pore size of the membrane as effective to remove toxic substances from the blood (see ***MPEP sections 2131.03 and 2144.05).***

Claims 1,2,5-7 and 10-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Matson patent 6,736,972.

Patent '972 concerning a different inventive entity with an earlier effective priority date discloses for claims 1,5,6 and 11, a replacement fluid for therapeutic use to replace a portion of blood being hemofiltered (column 14, line 53-column 15, line 38). The fluid consists of clean, target receptor molecules including activated protein, receptor antagonists and antibodies.

For claims 2,6,11 through 17 a very large pore hemofilter 702 is used (column 16, lines 10-13).

For claims 5 and 10, the fluid may contain plural types of target receptor molecules (column 16, lines 15-18).

For claim 11, see coupling 734 and column 13, lines 1-2.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3,4,8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bene et al in view of Rausch et al patent 5,905,141.

The claims differ in requiring the fluid to have a significant albumin concentration, such as taught by Rausch at column 59, lines 1-5. It would have been obvious to one of ordinary skill in the art to have included the albumin of Rausch within the replacement fluid of Bene et al, to treat the patient for acute toxicity.

Claims 12-14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bene et al in view of Lee et al.

These claims differ in requiring the membrane filter to have a relatively large MW cutoff to remove complex molecule, such being taught by Lee et al at column 2, lines 1-26 and 50-61 or column 4, lines 25-32 and 49-54. It would have also been obvious to one of ordinary skill in the art to have utilized the large MW cutoff membrane taught by Lee et al with the method or system of Bene et al, to remove toxic substances from the recirculated blood.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Drodge at telephone number 571-272-1140. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can reached at 571-272-1151. The fax phone number for the examining group where this application is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either private PAIR or Public PAIR, and through Private PAIR only for unpublished applications. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JWD

June 8, 2005

JOSEPH DRODGE
PRIMARY EXAMINER